

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of:	Nikolchev, et al.	Examiner:	Michael Brown
Application No.:	10/600,298	Group Art Unit:	3772
Filing Date:	June 20, 2003	Confirmation No.:	6671
For:	CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS		

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P.O. Box 1450  
Alexandria, VA 22313-1450

**SUGGESTION OF INTERFERENCE**  
**(RE U.S. PATENT NO. 6,432,116)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants respectfully suggest that an interference be declared with U.S. Patent No. 6,432,116 under 37 C.F.R. § 41.202 and that the following remarks be entered for the subject application.

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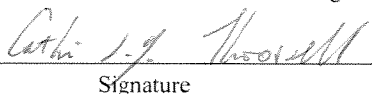
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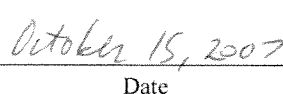
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## REMARKS

Applicants respectfully suggest that an interference be declared under 37 C.F.R. § 41.202 between the present application and U.S. Patent No. 6,432,116 (hereinafter “the ‘116 Patent”).

The effective filing date of the present application is earlier than that of the ‘116 patent, so that Applicants will be senior party in the suggested interference. The present application claims priority from U.S. Provisional Patent Application No. 60/059,861 (filed on September 24, 1997) as well as U.S. Patent Application Nos. 08/475,252 and 08/474,779 (both filed on June 7, 1995). As established below, support for the proposed count is found in the parent ‘779 and ‘252 applications originally filed on June 7, 1995 and in the 60/059,861 provisional application filed on September 24, 1997 (as well as in the instant application and the intervening parent applications). In contrast, the claims of the ‘116 patent are only entitled to a June 8, 1998 priority date as explained below.

### Showing in Support of Requested Interference

Under 37 C.F.R. § 41.202, Applicants suggest an interference be declared between the present application and the unexpired ‘116 Patent. Applicants have satisfied each requirement of § 41.202 as follows:

(1.) The patent with which Applicants are seeking an interference is U.S. Patent No. 6,432,116, which issued to Callister, *et al.* on August 13, 2002, and which is entitled Occluding Device and Method of Use.

(2.) The Proposed Count is as follows:

A contraceptive or sterilization device for occluding a reproductive body lumen to prevent the passage of reproductive cells therethrough, comprising:

a tubular member having a first end, a second end, and a lumen extending therein, which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and

a mesh member connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen.

The proposed Count is identical to claim 12 of the present application.

It is respectfully submitted that claims 1-20, 22, 23, 25, 28-46 of the '116 patent correspond to the Proposed Count because they would be anticipated or rendered obvious by the subject matter of the count if the count were treated as prior art. In addition, all pending claims of the present application (12-18, 35 and 36) correspond to the Proposed Count because they would be anticipated or rendered obvious by the subject matter of the count if the count were treated as prior art.

(3.) Claim Chart I below compares at least one claim of each party corresponding to the Count. In addition, Charts II and III below show why the claims interfere within the meaning of § 41.203(a).

**CHART I: A Claim Of Each Party That Corresponds To The Proposed Count**

<b>Claim 44 of U.S. Patent No. 6,432,116</b>	<b>Claim 12 of the Present Application</b>
A device for occluding a body lumen or passageway, comprising:	A contraceptive or sterilization device for occluding a reproductive body lumen to prevent the passage of reproductive cells therethrough, comprising:
a) a tubular member having a first end, and a second end, and a lumen extending therein, which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and	a tubular member having a first end, a second end, and a lumen extending therein, which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and
b) a tissue growth supporting member disposed within at least a section of the tubular member lumen, which is configured to support tissue growth to thereby occlude the body lumen or passageway.	a mesh member connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen.

**Interference Under § 41.203(a)**

Claim 44 of the '116 patent and claim 12 of the present application interfere under 37 C.F.R. § 41.203(a) because the subject matter of claim 44 of the '116 patent, if prior art, would have anticipated or rendered obvious claim 12 of the present application, and the subject matter of claim 12 of the present application, if prior art, would have anticipated or rendered obvious claim 44 of the '116 patent – as demonstrated in the claim charts below.

In determining the subject matter of the claims below (when treated as prior art in the 41.203(a) analysis), the claims are construed in light of the specification in which they appear and are given their “broadest reasonable construction” in light of that specification. 37 C.F.R. § 41.200(b); MPEP 2301.03.

## **CHART II**

<b>Claim 12 of Present App. Treated as Prior Art</b>	<b>Claim 44 of U.S. Patent No. 6,432,116</b>	<b>Interference under § 41.203(a)</b>
A contraceptive or sterilization device for occluding a reproductive body lumen to prevent the passage of reproductive cells therethrough, comprising: a tubular member having a first end, a second end, and a lumen extending therein, which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and a mesh member connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen.	A device for occluding a body lumen or passageway, comprising:	The subject matter of claim 12 of the present application anticipates the subject matter of this element. For example, claim 12 recites “ <i>a contraceptive or sterilization device for occluding a reproductive body lumen.</i> ”
	a) a tubular member having a first end, and a second end, and a lumen extending therein,	The subject matter of claim 12 of the present application anticipates the subject matter of this element. For example, claim 12 recites “a tubular member having a first end, a second end, and a lumen extending therein.”
	which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and	The subject matter of claim 12 of the present application anticipates the subject matter of this element. For example, claim 12 recites “which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration.”
	b) a tissue growth supporting member disposed within at least a section of the tubular member lumen, which is configured to support tissue growth to thereby occlude the body lumen or passageway.	The subject matter of claim 12 of the present application anticipates the subject matter of this element. For example, claim 12 recites “a mesh member connected to the tubular member, which is permeable to allow for tissue

		<p>ingrowth to thereby occlude the reproductive body lumen.”</p> <p>Claim 12’s mesh member has the same stated purpose as this element of claim 44 (to allow tissue ingrowth to occlude the lumen). In addition, the specification further clarifies that the mesh member supports tissue growth to occlude, e.g.: “providing an internal fabric 240 in the form of a textile mesh or felt inside the primary coil may be sufficient to incite ingrowth of the tubal tissues into the coil, affixing the coil in place and providing functional occlusion of the fallopian tube.”</p> <p>The mesh member of claim 12 therefore <i>is</i> a tissue growth supporting member and thus anticipates this element of the claim.</p>
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### CHART III

<b>Claim 44 of ‘116 Patent Treated as Prior Art</b>	<b>Claim 12 of the Present Application</b>	<b>Interference under § 41.203(a)</b>
<p>A device for occluding a body lumen or passageway, comprising:</p> <p style="padding-left: 20px;">a) a tubular member having a first end, and a second end, and a lumen extending therein, which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and</p> <p style="padding-left: 20px;">b) a tissue growth supporting member disposed</p>	<p>A contraceptive or sterilization device for occluding a reproductive body lumen to prevent the passage of reproductive cells therethrough, comprising:</p>	<p>The subject matter of claim 44 of the ‘116 patent anticipates or renders obvious the subject matter of this element. For example, claim 44 recites “A device for occluding a body lumen” that is placed in, and is expandable within, the “<i>reproductive</i> body lumen.”</p> <p>Inherent in the recited occlusion of a reproductive body lumen is the prevention of the passage of reproductive</p>

<p>within at least a section of the tubular member lumen, which is configured to support tissue growth to thereby occlude the body lumen or passageway.</p>		<p>cells and the resulting a contraceptive or sterilization effect.</p>
	<p>a tubular member having a first end, a second end, and a lumen extending therein,</p>	<p>The subject matter of claim 44 of the '116 patent anticipates the subject matter of this element. For example, claim 44 recites "a tubular member having a first end, and a second end, and a lumen extending therein."</p>
	<p>which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and</p>	<p>The subject matter of claim 44 of the '116 patent anticipates the subject matter of this element. For example, claim 44 recites "which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration."</p>
	<p>a mesh member connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen.</p>	<p>The subject matter of claim 44 of the '116 patent anticipates or renders obvious the subject matter of this element. For example, claim 44 recites "a tissue growth supporting member disposed within at least a section of the tubular member lumen, which is configured to support tissue growth to thereby occlude the body lumen or passageway."</p> <p>Claim 44's "tissue growth supporting member . . . configured to support tissue growth to thereby occlude," when interpreted in view of the specification of the '116 patent <u>is</u> a mesh member as recited in this element.</p> <p>The term "tissue growth supporting member" does not appear anywhere in the '116 specification. Instead, the</p>

	<p>'116 specification consistently and repeatedly refers to the member within the tubular member, which is permeable to allow for tissue growth, as "the mesh member." For example, the summary of the invention section begins: "This invention is directed to a device for occluding a body lumen, generally comprising a tubular member, and a mesh member transversely disposed on the tubular member which is permeable to allow for tissue ingrowth" ('116 patent 1:32-35).</p> <p>In every embodiment described in the specification, the member which is permeable and supports tissue growth to occlude is labeled as number "15" and is always referred to as the "mesh member."</p> <p>Even when the specification lists alternatives for the member that supports tissue growth to occlude, that member is still referred to as "the mesh member," e.g., "<i>The mesh member</i> is formed from a biocompatible material, such as a metal, polymeric material, and organics such as animal tissues, and is preferably reactive to tissue so as to promote the tissue ingrowth into <i>the mesh member</i>" ('116 patent, 2:11-15).</p> <p>Because claim 44's "tissue growth supporting member" is not a term of art and because</p>
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		<p>the '116 specification describes no alternative tissue growth supporting members, tissue growth supporting member is properly construed to disclose a mesh member that anticipates this element of the claim.</p> <p>Even if the tissue growth supporting member of claim 44 were somehow interpreted to encompass more than a mesh member, the choice of mesh as a suitable, permeable member to support tissue growth to occlude the lumen would have been obvious to a person of skill in the art.</p> <p>This is consistent with the position taken by the Patent Office during the prosecution of the '116 patent. Specifically, in an Office Action dated May 24, 2000, the Examiner issued a double patenting rejection against what later became the '116 patent claims—based on the claims of Application No. 09/112,085 (which subsequently issued as the '052 patent). Claim 12 of the present application is identical to claim 28 of Application No. 09/112,085, thus, the Patent Office has already determined that the '116 patent's claim 44 is not patentably distinct from claim 12.</p>
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(4.) Applicants will prevail on priority at least because they have an earlier constructive reduction to practice date. As mentioned above, the effective filing date of the



present application is earlier than that of the '116 patent so that Applicants will be the senior party in the requested interference. The present application claims priority from provisional application 60/059,861 filed on September 24, 1997, which has the same relevant disclosure as the present application. Furthermore, Applicants are entitled to an effective filing date of June 7, 1995 because the subject matter of the proposed count is supported by Applicants' 1995 priority filings (Application Ser. Nos. 08/475,252 and 08/474,779). In contrast, the '116 patent issued from an application filed on December 21, 1999, which claims priority to Application No. 09/112,085, filed July 8, 1998. The first paragraph of the '116 patent specification also claims priority to Application No. 08/770,123 filed December 18, 1996 (hereinafter "the '123 application"), but it is unclear whether this priority claim is proper or effective. Regardless, the '123 application does not provide support for the claims of the '116 patent or the proposed count. For example, the '123 application does not disclose the limitation of the count: "a mesh member connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen." Instead, the '123 application describes a device that allegedly provides contraception through its tubular member collapsing on itself or on a plug. Accordingly, the earliest priority date the '116 patent can be accorded for the subject matter of the count is July 8, 1998—well after the effective filing date of Applicants for the same subject matter. Further, even if the '116 patent was entitled to the December 18, 1996 priority date, the present application is entitled to a June 7, 1995 priority date.

(5.) Claims 12-18, 35 and 36 correspond to the proposed count and were added to this application to provoke an interference. Because the present application claims priority from App. Ser. Nos. 08/474,779 and 08/475,252 and incorporates by reference their disclosures,<sup>1</sup> the support detailed in Addendum A for the purpose of demonstrating constructive reduction to

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<sup>1</sup> Application Nos. 09/093,835 and 08/475,252, which are specifically incorporated by reference into the present application, contain the disclosure of Application No. 08/474,779 through incorporation by reference.

practice (for section 6 below) also demonstrates written description support in the instant application for claims 12-18, 35 and 36.

(6.) Addendum A contains claim charts detailing examples of written description support for the subject matter of the proposed count (claim 12) in parent App. Ser. No. 08/474,779 (filed June 7, 1995). Addendum A also includes claim charts detailing examples of written description support for the rest of claims 13-18, 35 and 36 in Applicants' June 7, 1995 filings.

CONCLUSION

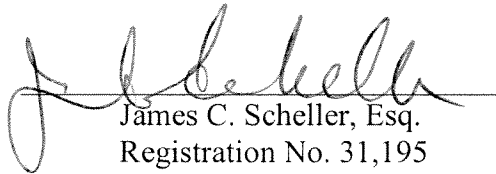
In view of the above, Applicants respectfully request that an Interference with the '116 patent be declared.

The Commissioner is hereby authorized to charge any required fee and/or credit any overpayment to Deposit Account Number 02-2666.

Respectfully submitted,  
BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: Oct. 15, 2007

By:

  
James C. Scheller, Esq.  
Registration No. 31,195

1279 Oakmead Parkway  
Sunnyvale, CA 94085-4040  
(408) 720-8300 Phone  
(408) 720-8383 Fax

## **ADDENDUM A**

### **Specification Support for Corresponding Claims**

<b>Claim 12</b>	<b>Examples of Support in Parent Applications</b>
A contraceptive or sterilization device for occluding a reproductive body lumen to prevent the passage of reproductive cells therethrough, comprising:	See, e.g., 08/474,779, page 3, lines 29-37; page 8, lines 9-22.
a) a tubular member having a first end, a second end, and a lumen extending therein, which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and	See, e.g., 08/474,779, Figs. 4, 6; page 9, lines 13-22; page 10, lines 30-38; page 11, lines 1-7; page 12, lines 16-30.
b) a mesh member connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen.	See, e.g., 08/474,779, page 5, lines 4-8; page 8, lines 20-22; page 10, lines 5-17.

<b>Claim 13</b>	<b>Examples of Support in Parent Applications</b>
A contraceptive device installed within a lumen of the patient's reproductive system, comprising	See, e.g., 08/474,779, page 3, lines 29-37; page 8, lines 9-22.
a) a tubular member having a first end, a second end, and a lumen extending therein, and having at least a portion thereof which is secured to a body wall portion defining at least in part the lumen of the patient's reproductive	See, e.g., 08/474,779, page 9, lines 13-22; page 13, lines 16-27.

<b>Claim 13</b>	<b>Examples of Support in Parent Applications</b>
system; and	
b) an occluding member connected to the tubular member comprising an epithelialized mesh which occludes the lumen of the patient's reproductive system sufficiently to prevent the passage of reproductive cells therethrough.	See, e.g., 08/474,779, page 5, lines 4-8; page 8, lines 9-22; page 10, lines 5-17.

<b>Claim 14</b>	<b>Examples of Support in Parent Applications</b>
A contraceptive system, comprising	See, e.g., 08/474,779, page 6, lines 12-15.
a) a catheter having a proximal end, a distal end, and a lumen extending at least in part therein; and	See, e.g., 08/474,779, Fig. 3; Fig. 4; page 11, lines 26-30.
b) a contraceptive device releasably connected to the catheter, having a tubular member having a first end, a second end, and a lumen extending therein, which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration, and having a mesh member connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen.	See, e.g., 08/474,779, Fig. 4; page 12, lines 4-19; page 9, lines 13-22; page 12, lines 16-30; page 5, lines 4-8; page 8, lines 13-22; page 10, lines 5-17.

<b>Claim 15</b>	<b>Examples of Support in Parent Applications</b>
A method of contraception comprising	See, e.g., 08/474,779, page 3, lines 29-30;

<b>Claim 15</b>	<b>Examples of Support in Parent Applications</b>
the steps of:	page 6, lines 30-34.
a) inserting within a desired body lumen a contraceptive device comprising a tubular member and a mesh member connected thereto;	See, e.g., 08/474,779, Fig. 5; Fig. 6; page 13, lines 3-15; page 9, lines 13-22; page 5, lines 4-8; page 8, lines 13-22; page 10, lines 5-17.
b) expanding the tubular member within the body lumen;	See, e.g., 08/474,779, Figs. 4-6; page 12, lines 16-30.
c) securing the expanded tubular member to a wall portion defining at least in part the body lumen; and	See, e.g., 08/474,779, Figs. 5-6; page 13, lines 16-27.
d) epithelializing the mesh member to occlude the body lumen.	See, e.g., 08/474,779, page 5, lines 4-8; page 8, lines 13-22; page 10, lines 5-17.

<b>Claim 16</b>	<b>Examples of Support in Parent Applications</b>
The method of claim 15 wherein the step of expanding the tubular member comprises the step of releasing a radially compressive force on the tubular member.	See, e.g., 08/474,779, Fig. 4, page 12, lines 4-19.

<b>Claim 17</b>	<b>Examples of Support in Parent Applications</b>
The method of claim 16 wherein the contraceptive device is disposed within a lumen of a delivery catheter, and the step of releasing the radially compressive force comprises longitudinally displacing the tubular member out a distal end of the delivery	See, e.g., 08/474,779, Fig. 3; Fig. 4; page 12, lines 20-22; page 13, lines 16-21.

<b>Claim 17</b>	<b>Examples of Support in Parent Applications</b>
catheter.	

<b>Claim 18</b>	<b>Examples of Support in Parent Applications</b>
The method of claim 15 wherein the expanded tubular member is disposed within the body lumen for sufficient time for it to be epithelialized within the body lumen and thereby secured to the wall portion.	See, e.g., 08/474,779, page 10, lines 5-17.

<b>Claim 35</b>	<b>Examples of Support in Parent Applications</b>
A sterilization device occluding a reproductive body lumen to prevent the passage of reproductive cells therethrough, comprising:	See, e.g., 08/474,779, page 3, lines 29-37; page 8, lines 9-22.
a) a tubular member having a first end, a second end, and a lumen extending therein, the tubular member at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and	See, e.g., 08/474,779, Fig. 4; page 9, lines 13-22; page 12, lines 16-30.
b) a mesh member connected to the tubular member, the mesh member permeable and receiving tissue ingrowth therein so as to occlude the reproductive body lumen.	See, e.g., 08/474,779, page 5, lines 4-8; page 8, lines 20-22; page 10, lines 5-17.

<b>Claim 36</b>	<b>Examples of Support in Parent Applications</b>
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<p>A contraceptive device installed within a lumen of the patient's reproductive system, comprising:</p>	<p>See, e.g., 08/474,779, page 3, lines 29-37; page 8, lines 9-22.</p>
<p>a) a tubular member having a first end, a second end, and a lumen extending therein, and having at least a portion thereof which is secured to a body wall portion defining at least in part the lumen of the patient's reproductive system; and</p>	<p>See, e.g., 08/474,779, page 9, lines 13-22; page 13, lines 16-27.</p>
<p>b) an occluding member connected to the tubular member comprising a mesh receiving tissue ingrowth therein, the ingrown mesh occluding the lumen of the patient's reproductive system sufficiently to prevent the passage of reproductive cells therethrough.</p>	<p>See, e.g., 08/474,779, page 5, lines 4-8; page 8, lines 13-22; page 10, lines 5-17.</p>